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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,546	03/09/2001	Debi Whitson	36357	8651

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HOVEY WILLIAMS LLP
2405 GRAND BLVD., SUITE 400
KANSAS CITY, MO 64108

EXAMINER

PORTER, RACHEL L

ART UNIT	PAPER NUMBER
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3626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/802,546

Applicant(s)

WHITSON, DEBI

Examiner

Rachel L. Porter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-11,13,14 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-7,9-11,13-14,17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 12/1/06. Claims 1-2, 4-7,9-11,13-14,17-21 are pending.

Claim Rejections - 35 USC § 112

2. The rejection of claim 1-2, 4-7,9-11,13-14, and 17 under 35 U.S.C. 112, second paragraph, is hereby withdrawn due to the amendment filed 12/1/06.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,4-6,9,11,13-14, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable Kimak (USPAP 2005/0187794 A1) over Kraftson et al (USPN 6,151,581-hereinafter Kraftson).

[claim 1] Kimak discloses a process of forming an electronic medical record, the method comprising of the steps of:

- c) arranging the data stream of patient data into a defined data structure
simulating the protocol structure from a party having authorization to export data to

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the patient's patient specific medical record; (par. 47-48, par. 64-65, par. 70-71; Figure 3)

d) sending the formatted data to an assigned location for importing into the patient's patient-specific medical record, wherein the electronic medical record contains specific information regarding the patient's health (par. 66-67, par. 70) Kimak further disclose obtaining patient information from disparate sources (par. 68,71) but does not expressly disclose that the data is obtained by providing the patient with a machine-readable questionnaire concerning the patient's health.

Kraftson discloses :

- a) providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67)
- b) interfacing a machine readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream; (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

Claim 1 has been further amended to recite providing the patient with a machine readable card including a questionnaire.

Kraftson discloses a process further comprising providing the patient with a the machine-readable card including a questionnaire (i.e is a paper answer sheet comprised of questions with designated areas for patient responses.) (Figures 2A-

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C, col. 7, lines 3-11). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to include machine-readable card including a questionnaire. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

[claim 4] Kimak and Kraftson teach the method of claim 1 as explained in the rejection of claim 1. Furthermore, Kraftson teaches a process wherein the machine-readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses and is accomplished by a member of the clinical staff. (Figures 2A-C; 3A-C; Figure 13—Receptionist/staff helps provide patient questionnaire.) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson for the reasons set forth in the rejection of claim 1.

[claim 5] Kimak and Kraftson teach the method of claim 1 as explained in the rejection of claim 1. Kraftson teaches a process wherein the step of interfacing the machine-readable card with the scanning type machine is accomplished by a member of the clinical staff. (col. 6, lines 1-10; col. 7, lines 3-10; col. 20, lines 5-8,

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lines 43-69 (e.g. Clinical staff member receives E-PDS and downloads the information patient information by connecting to the host device) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson for the reasons set forth in the rejection of claim 1.

[claims 6] Kimak discloses a process, further comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66)

[claim 9] Kimak teaches a process further comprising a step of receiving the formatted data with an interface engine (par. 57-58) and sending it to the database containing the patient's electronic medical record. (par. 65-67)

[claim 11] Kimak and Kraftson teach the process of claim 4 as explained in the rejection of claim 4. Furthermore, Kraftson discloses a process wherein the machine-readable card is a paper answer sheet comprised of questions with designated areas for patient responses. (Figures 2A-C, col. 7, lines 3-11). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to include a paper survey for the motivation provided in the rejection of claims 1 and 4.

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[claim 13] Kimak discloses the method of claim 9 wherein said database is any database that accepts HL7 or ASTM messaging. (par. 34, par. 66)

[claim 14] Kimak and Kraftson disclose the method of claim 1 as explained in the rejection of claim 1. Kimak further discloses a process comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66) disclose receiving the data stream from the scanning type device.

However, at the time of the Applicant's device, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak and Kraftson to accept the data stream from the scanning device. One would have been motivated to include this feature to facilitate the transfer electronic medical records from heterogeneous sources into a central registry. (Kimak: par. 3)

[claim 18] Kimak discloses a method for supplementing a medical record with medical information comprising the steps of:

- communicating the formatted data to an electronic medical record interface and adding the information to the patient's personal medical record, wherein the patient's personal medical record contains patient specific, clinical information regarding the patient's health; and (par. 47, 63-66)
- presenting the information to a physician as part of the patient's personal electronic medical record. (par. 87)

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Kimak discloses obtaining patient information from disparate sources (par. 68,71) but does not expressly disclose that the data is obtained by providing the patient with a machine-readable questionnaire concerning the patient's health.

Kraftson discloses a method of obtaining patient information with information submitted by a patient, the method comprising the steps of:

- receiving from the patient a machine-readable printed form containing information about a health status of the patient; (Figures 2A-2C, 3A-3C,13; col. 5, line 65-col. 6, line 3; col. 11, lines 43-58; col. 14, lines 28-67)
- electronically scanning the printed form to convert the information to machine processable data and communicate the data to a computer; (Figures 1 and 4; col. 7, lines 3-10)
- formatting the machine-processable data with the computer so that the data is in a form that may be communicated to an electronic medical record; (col. 7, lines 6-10; col. 9, lines 32-49; col. 13, lines 59-61)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

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[claim 19, 21] Kimak discloses presenting the patient's electronic medical record to the physician, before the patient visits the doctor to apprise the physician of the patient's health status in the patient's absence. (par. 47, 76, and 86). However, Kimak does not expressly disclose that the data is obtained from a questionnaire or that the questionnaire is mailed to a patient prior to an appointment. Kraftson discloses a method, further comprising the step of mailing the form to the patient prior to the appointment; and (col. 11, lines 9-13—Patients see doctors for the first time or on an ongoing basis to update information and may opt to fill out survey prior to any of their appts.) At the time of the Applicant's invention, it would have been to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to mail a form/questionnaire to the patient to be completed before an appointment. As suggested by Kimak, one would have been motivated to include this feature to allow the point of care providers to become more informed and to become part of a network is updated with medical (e.g. immunization) information. (par. 47)

[claim 20] The limitations of claim 20 are substantially similar to claims 14 and 18. As such, claim 20 is addressed by the rejections of claims 14 and 18, and incorporated herein.

5. Claims 2, 10, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimak and Kraftson as applied to claim 1 above, and further in view of Oyama et al (USPN 5,496,175).

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[claims 2 and 10] Kimak and Kraftson teaches a system/method of gathering and entering patient data into a patient database using professional staff members, (col. 7, lines 3-11) but does not expressly disclose inputting information using a microcomputer compatible keyboard. Oyama discloses a questionnaire system wherein data gathering and input of questionnaire/survey data occurs using PC's with keyboards (col. 6, lines 21-36) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson with the teaching of Oyama to allow manual input of data using a keyboard. As suggested by Oyama, one would have been motivated to include these features to increase the diversity of information that may be input into the system from the questionnaire data. (col. 1, line 55-col. 2, line 2).

[claim 17] Kimak and Kraftson teach a process wherein the computer processor is a standard PC (col. 8, lines 60-63; col. 19, lines 21-25). Kimak and Kraftson do not expressly disclose the specifications of the computer. However, Applicant provides no explanation in the specification as to why the recited specifications (32 MB of hard drive space and a processor capable of operating at 100 MHz) provide an advantage over other processor speeds and memory requirements. Moreover, it is respectfully submitted that at the time of the applicant's invention, a hard drive with at least 32 MB of memory and a processor with at least a 100 MHz processor were well known in the computer arts. At the time of the Applicant's invention, it

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would have been obvious to one of ordinary skill in the art to include a computer with at least 32 MB of hard drive memory and at least a 100 MHz processor speed in the system of Kraftson and Oyama in combination with the motivation of making the method available to medical practices and individuals with limited computer resources.

6. Claim 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimak and Kraftson as applied to claim 1 above, and further in view of Applicant's Admission of prior art (page 8, lines 6-8 of 6/20/06 Applicant's response.)

[claim 7]

Kimak and Kraftson disclose the method of claim 1 as explained in the rejection of claim 1. Kraftson discloses a survey system and method for obtaining patient information from a questionnaire (Figure 2A-2C; col. 5, line 65-col. 6, line 3) and converting the obtained information into a data stream (col. 6, line 5-10; col. 7, lines 3-10; Figure 4), but does not expressly disclose the specific formats that are accommodated by the system. However, it is noted that HL7, ANSI, and ASTM are well known in the art for establishing transmitting and formatting standards for data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kimak and Kraftson in combination to accommodate HL7, ANSI or ASTM protocol standards. One would have been motivated to include this feature to facilitate the transmission, storage, and analysis of patient data, as suggested by Kraftson (col. 2, lines 56-63).

Response to Arguments

7. Applicant's arguments filed 12/1/06 have been fully considered but they are not persuasive.

(A) Applicant argues the combination of Kimak and Kraftson, stating that *prima facie* case of obviousness has not been established.

In response, In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner submits that motivations have been provided for each of the combinations, which support the holding of obviousness. In each case, the motivations for the combinations are found in one or more the references themselves or would have been in the knowledge generally available to one of ordinary skill in the art.

(B) Applicant further argues that Kraftson is non-analogous to the applicant's invention.

In response to applicant's argument that Kraftson is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for

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rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both the applicant's invention and the Kraftson reference are drawn to medical surveys, and are therefore in the same field of endeavor. In particular, both inventions are deal with "providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, **or other pertinent information for answering by the patient**; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67)" and "interfacing a machine readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream," and are therefore attempting to address some of the same problems in the art. As such, the Kraftson reference is not seen as a non-analogous reference.

Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(C) Applicant argues that Kimak does not "import information" into the patient's record.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

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(i.e., "import information into a patient's record...") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). (The Examiner presumes the Applicant is arguing the limitations of claim 1). It is noted that the last positively recited step in claim 1 is the "sending of formatted data to an assigned location..." The claim does not recite actively recite a step of "importing patient data..."

Also, it is unclear to the patient data in the Kimak reference is "gleaned" without data being imported during the data transmission process.

(D) Applicant further argues that Kimak does not receive data from users, only remote servers.

Again, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., receiving data directly from users) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, the term "users" is an encompassing phrase which would include server owners/operators, and physicians, as well as patients.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RP


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